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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,061	02/03/2006	Francisco Javier Vila Pahi	Q92724	9539

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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
09/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,061	VILA PAHI ET AL.	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/03/06 & 03/02/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 10-18 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

A written description analysis involves three principle factors:

(1) field of the invention

(2) breath of the claims, and

(3) possession of the claimed invention at the time of filing for each claimed species/genus based upon the teachings of the specificaiton and the field of the invention.

The Federal Circuit court stated that written description of an invention "requires a precise definition, such as by structure, formula, or chemical name, of the claimed subject matter sufficient to distinguish it from other material". University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed Cir. 1997). The court also stated "Naming a type of material generally known to exist, in the absence as to what the material consists of is not a definition of that material". Id. Further, the court stated that to adequately describe a claimed genus, adequate

must describe a representative number of species of the claimed genus, and that one skilled in the art should be able to "visualize or recognize the identity of the members of the genus". Id .

(A) Provide a brief backdrop of the field of the invention. A reference from the BACKGROUND might very well be sufficient.

(B) Outline the scope and content of the claims briefly

(C) At the time of filing, from the disclosure, does it appear applicants were indeed in possession of the claimed invention?

The claims are drawn to a method of treatment or prevention of psoriasis with skin affection in a mammal, comprising administering to a mammal in need thereof an effective amount of an alkaline or alkaline earth metal chondroitin sulfate obtained from enzymatic hydrolysis of animal cartilage. The examiner notes that the knowledge and level of skill in this art would not permit one skilled in this art to assert a preventive therapeutic mode of administration and the skilled artisan could not immediately envisage the invention claimed. Applicants claims are drawn to method of prevention of psoriasis with skin affection in a mammal, comprising administering to a mammal in need thereof an effective amount of an alkaline or alkaline earth metal chondroitin sulfate obtained from enzymatic hydrolysis of animal cartilage, which is not generally known to exist in this art; additionally, the disclosure is silent with regard to that which makes up and identifies the claimed method for preventing the said diseases, which is seen to be lacking a clear description via art recognized procedural and methodological steps. In addition, the prevention of such diseases does not have a single recognized cause. Moreover, the cause of psoriasis is not known, but it is believed to have a genetic component and is hypothesized to be immune-mediated and not contagious. Furthermore, psoriasis is a chronic *recurring condition* which varies in severity from minor

localised patches to complete body coverage. In fact, the aforementioned disease, is recognized as having many contributing factors, ranging from hereditary considerations, to lifestyle choices such as the diet and maintenance of bodily healthiness which includes climate, skin injury, stress and anxiety, infection and certain medication, such as NSAIDs, beta-blockers, and lithium. These are only a few of the factors that promote these diseases in people. Applicant has not provided a description as how any cause (like the aforementioned) can be prevented, much less a description of how the said disease or condition can be prevented. Furthermore, Applicant has not provided any clear description via art recognized procedural and methodological steps. Moreover, Applicant has not provided an adequate representation of the mode of treatment of said diseases or condition to provide a full, clear and precise indication that applicant is in possession of the members of the methodological and procedural steps which would enable the skilled artisan to practice this invention by preventing said diseases. It should be noted that dependent claims 11-18 which are drawn to a method of preventing the said disease or condition are also encompassed by the aforementioned rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "psoriasis with skin affection" in claim 10 renders the claim indefinite. More specifically, it is unclear what type of psoriasis is being referred or what type of psoriasis is not encompassed by said phrase or claim since psoriasis is a skin affection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al. (WO 01/83707 A2).

In claim 10, applicant claims a method of treatment or prevention of psoriasis with skin affection in a mammal, comprising administering to a mammal in need thereof an effective amount of an alkaline or alkaline earth metal chondroitin sulfate obtained from enzymatic hydrolysis of animal cartilage. Claims 11-18 are drawn to said method wherein the said chondroitin sulfate is obtained from a specific source, it is sodium chondroitin sulfate, it is of specific molecular weight range, specific sulfur content and wherein the administration is by specific routes.

Olsen et al. disclose that psoriasis in a mammal (human or animal) can be treated by administering to said mammal chondroitin sulfate (see claims 47 and 49; see also claims 1-5). Olsen et al. disclose that the chondroitin sulfate can be obtained from animal cartilage (see claims 2 and 5). It should be noted that the source of the chondroitin sulfate does not further limit the chondroitin sulfate used.

The difference between applicant's claimed method and the method suggested by Olsen et al. is that applicant uses an alkaline or alkaline earth metal chondroitin sulfate. However, Olsen et al. suggest that a pharmaceutically acceptable salt (which includes alkaline or alkaline earth metal salts such as the common sodium metal salt) can be used (page 18, lines 16-21).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the method suggested by Olsen et al. to administer a pharmaceutically acceptable salt of chondroitin sulfate such as sodium chondroitin sulfate to treat psoriasis in a mammal, since Olsen et al. suggest that a pharmaceutically acceptable salt can be used to treat the same said conditions.

One having ordinary skill in the art would have been motivated to use the method suggested by Olsen et al. to administer a pharmaceutically acceptable salt of chondroitin sulfate such as sodium chondroitin sulfate to treat psoriasis in a mammal, since a skilled artisan would reasonable expect to use the composition taught by Olsen et al. for the same said purpose. It should be noted that the use of specific routes of administration such as topical or oral administration depends on factors such as the severity and location of the psoriasis treated, the type, age and size of mammal. It should be noted that the use of sodium chondroitin sulfate of specific molecular weight and of specific dosage, amount or sulfur content depends on factors such as the severity of the psoriasis treated and the type, age and size of mammal.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the

examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

9/12/07

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

September 12, 2007.